

## **REMARKS**

Applicants have amended claims 60, 68, 70, 79, 113, and 114 to add recitations in the interest of advancing prosecution. In addition, Applicants have amended claims 67 and 78 to place them in independent form and canceled claims 115 and 117 without prejudice or disclaimer. Further, Applicants have added new claims 118-121, which are readable on the previously elected “species” as well as being generic to other species. Claims 60, 61, 63-68, 70-72, 74-79, 113, 114, 116, and 118-121 are pending.

### **I. The Section 102(e) Rejection Based on Villani Should Be Withdrawn**

In the Office Action, claims 60, 61, 63-68, 70-72, and 74-79 were rejected under 35 U.S.C. § 102(e) based on U.S. Patent No. 5,848,989 to Villani (“Villani”). The Office Action at pages 2-4 cites “the middle section of element 6” of Villani for the asserted disclosure of an access site, and reference numerals 9 and 7 of Villani for the asserted disclosure of an outlet and an entry site, respectively.

Applicants respectfully submit that the Section 102(e) rejection should be withdrawn because Villani does not disclose the subject matter recited in independent claims 60, 67, 70, and 78.

#### **A. Independent Claims 60 and 70 Are Allowable Over Villani**

Although Applicants respectfully disagree with the Section 102(e) rejection of independent claims 60 and 70 based on Villani, Applicants have added further recitations to claims 60 and 70 in an attempt to advance prosecution. Villani does not disclose or suggest an access port device including, among other features, an access site, an entry site, and an outlet, “wherein the device is configured to permit access, from an exterior of the device, to [a] reservoir via the access site without passing through the entry site and without passing through the outlet,” as recited in amended

independent claims 60 and 70. No such configuration is disclosed in Villani. For example, even if the “middle section of element 6” of Villani were to be equated with an access site, as asserted in the Office Action at p. 3,<sup>1</sup> “the middle section of element 6” would not permit access, from an exterior of Villani’s port 1, to Villani’s reservoir 8 without passing through Villani’s housing inlet 7, which the Examiner equated with the recited entry site, and without passing through Villani’s outlet 9.

For at least these reasons, claims 60 and 70 are allowable over Villani.

**B. Independent Claims 67 and 78 Are Allowable Over Villani**

Villani also does not disclose a device “configured to permit access to [a] reservoir via [an] access site without passing through [an] entry site,” and including a “septum [that] comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.” The Office Action does not provide any meaningful explanation of why claims 67 and 78 were rejected based on Villani. Contrary to the general assertion in the Office Action at p. 3, Villani’s septum 4 does not include a first septum portion providing access to a reservoir via an entry site and a second septum portion providing access to the reservoir via an access site. For example, as illustrated by Fig. 3 of Villani, which shows a needle 13 passing through the septum 4 via inlet 7, the septum 4 only permits access to the reservoir 8 via the inlet 7, which the Examiner

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<sup>1</sup> Applicants respectfully submit such an interpretation of Villani is improper. See, e.g., the Pre-Appeal Brief Request for Review filed January 22, 2007, at pp. 1-2.

equated with the recited entry site. The septum 4 does not have a second portion permitting access to the reservoir 8 via an access site.

For at least these reasons, claims 67 and 78 are allowable over Villani.

**C. Dependent Claims 61, 63-66, 68, 71, 72, 74-77, and 79 Also Are Allowable Over Villani**

Claims 61, 63-66, and 68 depend from claim 60 and claims 71, 72, 74-77 and 79 depend from claim 70. Accordingly, those dependent claims should be allowable over Villani for at least the reasons discussed above in connection with claims 60 and 70.

**II. The Section 102(b) Rejection Based on Kirsch Should Be Withdrawn**

In the Office Action, claims 60, 61, 63-68, 70-72, 74-79, and 113-117 were rejected under 35 U.S.C. § 102(b) based on U.S. Patent No. 5,385,541 to Kirsch et al. (“Kirsch”).

Applicants respectfully submit that the Section 102(b) rejection based on Kirsch should be withdrawn because Kirsch does not disclose all of the features recited in independent claims 60, 67, 70, 78, 113, and 114.

**A. Independent Claims 60 and 70 Are Allowable Over Kirsch**

Kirsch does not disclose or suggest an access port device including, among other features, “a self-sealing septum between [an] upper body part and [a] lower body part,” as recited in claims 60 and 70. The Office Action cites reference numeral 31 of Kirsch for the asserted disclosure of a self-sealing septum. Nothing, however, supports this assertion. Rather than relating to a self-sealing septum, reference numeral 31 of Kirsch refers to a “pump tube” that can be manipulated by a physician to modify the flow rate of cerebrospinal fluid. See, e.g., Kirsch at col. 5, lines 17-28.

Kirsch also does not disclose or suggest a device including an access site and an outlet, “wherein the device is configured to permit access, from an exterior of the device, to [a] reservoir via the access site . . . without passing through the outlet,” as recited in amended independent claims 60 and 70. The Office Action cites reference number 33 of Kirsch for the asserted disclosure of an access site, reference numeral 36 for the asserted disclosure of an outlet, and “the area between 30 & 36” in Kirsch for the asserted disclosure of a reservoir. Even if Kirsch were to be interpreted in that manner (a notion that Applicants do not accept), Kirsch does not correspond to claims 60 and 70 because Kirsch’s distal end 33 does not permit access to the area between reference numerals 30 and 36 in Fig. 3 of Kirsch without passing through the valve 36 disclosed in Kirsch.

For at least these reasons, claims 60 and 70 are allowable over Kirsch.

**B. Independent Claims 67 and 78 Are Allowable Over Kirsch**

Similar to claims 60 and 70, claims 67 and 78 recite “a self-sealing septum between [an] upper body part and [a] lower body part.” As noted in the above explanation of why claims 60 and 70 are allowable over Kirsch, the Office Action fails to cite any portion of Kirsch corresponding to this recited feature. Accordingly, the rejection of claims 67 and 78 based on Kirsch should be withdrawn.

Kirsch also does not disclose or suggest a device “configured to permit access to [a] reservoir via [an] access site without passing through [an] entry site,” and including a “septum [that] comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.” The Office Action does not provide any explanation of

why claims 67 and 78 were rejected based on Kirsch. In particular, the Office Action does not identify any alleged septum portions.

For at least these reasons, claims 67 and 78 are allowable over Kirsch.

**C. Independent Claims 113 and 114 Are Allowable Over Kirsch**

Similar to claims 60, 67, 70, and 78, claims 113 and 114 recite “a self-sealing septum between [an] upper body part and [a] lower body part.” As noted in the above explanation of why claims 60 and 70 are allowable over Kirsch, the Office Action fails to cite any portion of Kirsch corresponding to this recited feature. Consequently, the rejection of claims 113 and 114 based on Kirsch should be withdrawn.

Kirsch also does not disclose or suggest “one of a guidewire and a stylet,” as positively recited in claims 113 and 114. Contrary to the apparent assertion in the Office Action at p. 4, reference numeral 60 of Kirsch refers to a trocar such as a needle (see, e.g. Kirsch at col. 8, line 4 and at col. 9, lines 36-37), which is not necessarily the same as, and does not disclose a guidewire or a stylet. Moreover, even hypothetically if the trocar 60 of Kirsch were to be considered as being one of a guidewire and a stylet, Kirsch does not disclose a configuration that would permit inserting the Kirsch trocar 60 “through [a] body portion and into [an] outlet,” as recited in claims 113 and 114. For example, Kirsch lacks any disclosure of a configuration that permits an end of trocar 60 to pass through the valve 36 and the distal end 33 disclosed in Kirsch. Accordingly, Kirsch does not disclose the system recited in claims 113 and 114, and claims 113 and 114 are allowable over Kirsch.

**D. Dependent Claims 61, 63-66, 68, 71, 72, 74-77, 79, and 116 Also Are Allowable Over Kirsch**

Claims 61, 63-66, 68, and 116 depend from claim 60, and claims 71, 72, 74-77 and 79 depend from claim 70. Accordingly, those dependent claims should be allowable over Kirsch for at least the reasons discussed above in connection with claims 60 and 70.

**III. The Section 102(b) Rejection Based on Ensminger Should Be Withdrawn**

In the Office Action, claims 60, 61, 63-68, 70-72, 74-79, and 113-117 were rejected under 35 U.S.C. § 102(b) based on U.S. Patent No. 5,263,930 to Ensminger (“Ensminger”).

Applicants respectfully submit that the Section 102(b) rejection based on Ensminger should be withdrawn because Ensminger does not disclose all of the features recited in independent claims 60, 67, 70, 78, 113, and 114.

**A. Independent Claims 60, 70, 113, and 114 Are Allowable Over Ensminger**

Ensminger does not disclose or suggest a device (claims 60 and 70) or a system (claims 113 and 114) “configured so that when [an] outlet [of the device] is connected to [a] catheter, the reservoir is in continuous, unimpeded fluid communication with the catheter,” as recited in amended claims 60, 70, 113, and 114. Ensminger discloses a fluid chamber 20 associated with a leaflet-type valve 24 including a pair of resilient disks 28 and 30 having cuts that resists flow of antibacterial fluid from the fluid chamber 20. See, e.g. Ensminger at col. 4, line 48 through col. 5, line 20 and col. 6, lines 6-10. The valve 24 resists flow of fluid from the fluid chamber 20 to an outlet nipple 42 and a catheter 44. Consequently, Ensminger does not have a configuration in

which a “reservoir is in continuous, unimpeded fluid communication with [a] catheter,” as recited in claims 60, 70, 113, and 114.

For at least these reasons, claims 60, 70, 113, and 114 are allowable over Ensminger.

**B. Independent Claims 67 and 78 Are Allowable Over Ensminger**

Kirsch also does not disclose or suggest a device including a “septum [that] comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.” The Office Action does not provide any explanation of why claims 67 and 78 were rejected based on Ensminger. For example, the Office Action does not identify any alleged septum portions. The septum 56 of Ensminger does not provide access to a reservoir via Ensminger’s entrance orifice 14, which the Examiner apparently equated with the recited entry site.

For at least this reason, claims 67 and 78 are allowable over Ensminger.

**C. Dependent Claims 61, 63-66, 68, 71, 72, 74-77, 79, and 116 Also Are Allowable Over Ensminger**

Claims 61, 63-66, 68, and 116 depend from claim 60, and claims 71, 72, 74-77 and 79 depend from claim 70. Accordingly, those dependent claims should be allowable over Ensminger for at least the reasons discussed above in connection with claims 60 and 70.

**IV. The Section 103(a) Rejection Based on Villani and Kirsch Should Be Withdrawn**

In the Office Action, claims 113-117 were rejected under 35 U.S.C. § 103(a) based on Villani in view of Kirsch.

Applicants respectfully submit that the Section 103(a) rejection of claims 113 and 114 should be withdrawn because neither Villani, nor Kirsch, nor any combination thereof discloses or suggests “one of a guidewire and a stylet,” as positively recited in claims 113 and 114. As apparently acknowledged in the Office Action at p. 5, Villani does not disclose a guidewire or stylet. Contrary to the assertion in the Office Action at p. 5, Figs. 7 and 8 of Kirsch do not provide any teaching of a guidewire. As explained above in the remarks addressing the Section 102(b) rejection of claims 113 and 114 based on Kirsch, reference numeral 60 of Kirsch refers to a trocar such as a needle (see, e.g. Kirsch at col. 8, line 4 and at col. 9, lines 36-37), which is not necessarily the same as, and does not disclose a guidewire or a stylet. Moreover, even hypothetically if the trocar 60 of Kirsch were to be considered as being one of a guidewire and a stylet, Kirsch does not disclose a configuration that would permit inserting the Kirsch trocar 60 “through [a] body portion and into [an] outlet,” as recited in claims 113 and 114. For example, Kirsch lacks any disclosure of a configuration that permits an end of trocar 60 to pass through the valve 36 and the distal end 33 disclosed in Kirsch. Accordingly, Villani and Kirsch do not disclose or suggest the system recited in claims 113 and 114.

Moreover, one of ordinary skill in the art would not have had any legitimate reason to combine the Villani and Kirsch references. Villani is directed to an implantable port. In contrast, Kirsch is directed to a cerebrospinal fluid shunt. One of ordinary skill in the art would not have had any plausible reason to combine features of these references relating to dissimilar subject matter. In particular, there would have been no reason to use Kirsch’s trocar in the form of a needle “to help guide the needle 13” disclosed in Villani, as asserted in the Office Action. Indeed, the Office



Action fails to explain why one of ordinary skill in the art would have any interest in using a needle to “help guide” a needle.

For at least these reasons, claims 113 and 114 are allowable over the purported combination of Villani and Kirsch.

Claim 116 depends from claim 60. As explained in the above sections addressing the Section 102(e) rejection based on Villani and the Section 102(b) rejection based on Kirsch, neither Villani nor Kirsch teaches or suggests the features recited in claim 60. Further, the proposed combination of those references has the same shortcomings. Accordingly, the Section 103(a) rejection of claim 116 should be withdrawn.

**V. New Claims 118-121 Are Allowable At Least Due to Their Dependency**

New claims 118-121 depend from claims 60, 70, 113, and 114, respectively. Accordingly, these dependent claims should be allowable for at least the same reasons as their respective base claims.

**VI. Conclusion: The Application is in Condition for Allowance**

Applicants respectfully request that the Examiner reconsider the application, withdraw all of the claim rejections, allow all of the claims, and issue a Notice of Allowability in a timely manner.

The Office Action contains a number of statements relating to the claims of the present application and the cited references. Applicants decline to subscribe to any statement in the Office Action, regardless of whether it might be specifically mentioned above.


If a telephone conversation might advance prosecution of the present application, the Examiner is invited to contact the undersigned (571-203-2774).

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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